

REMARKS

Claims 1-4, 6-11, 13-15, 17, 18, 21, 23, 25 and 27 are indicated as rejected in the Office Action. Claims 1, 6, 7, 8, 13, 17, 18, 21, 23, 25 and 27 are amended herein to clarify the subject matter of the invention. Claims 1-4, 6-11, 13-18, 21-23, 25 and 27 are now pending in this matter.

The foregoing claim amendments are provided in the interest of furthering the prosecution of this application. No art has been cited against the claims and the claim amendments are not made for any reasons relating to patentability.

Basis for the claim amendments and newly added claims is found throughout the specification. Applicants believe that no new matter is submitted by these claim amendments. Accordingly, Applicants respectfully submit that the claim amendments should be entered.

REJECTION UNDER 35 U.S.C. § 112 SECOND PARAGRAPH

Claims 17 and 21 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants submit that the claims prior to their amendment herein were definite because persons skilled in the art would have been readily able to ascertain the scope of the claimed invention. Nonetheless, Applicants amended their claims in an effort to expedite prosecution of the application. The amendments are intended to merely add consistency to certain portions of the claims, and they are not related to patentability of the claims. The amended claims continue to satisfy the definiteness requirements of 35 U.S.C. § 112, second paragraph.

With regard to claim 17, the Examiner asserts that the claim "does not make clear that the plurality of promoter sequences that drives expression of the gene at steps of 50-100% does so in the same microorganism as in which the conserved sequences were

identified . . . [t]hus there is no clear antecedent basis for the host cell in the limitation of covering a range of promoter activities." Office Action, page 11.

Applicants have amended claim 17 to clarify that the microorganism of claim 17 is the same as that of claim 16, in accordance with the Examiner's suggestions. See Office Action, page 11. Accordingly, Applicants respectfully submit that this amendment obviates the foregoing basis for the rejection of claim 17.

The Examiner also asserts that claim 21 lacks "clear and positive prior antecedent basis for the term 'the pathway' in the preamble of the claim." Office Action, page 11. Claim 21 has been amended to recite "a pathway" instead of "the pathway". Accordingly, Applicants respectfully submit that the amendment obviates the basis for the rejection of claim 21.

In view of the foregoing amendments and remarks, Applicants respectfully request that the Examiner reconsider and withdraw the rejection. The Examiner is welcomed to contact the undersigned, if further clarification in the claims is believed to be required.

**REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH
(LACK OF ADEQUATE WRITTEN DESCRIPTION)**

Claims 1-4, 6-11, 13-15, 18, 23, 25 and 27 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants submit that the claims prior to their amendment herein were described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for at least the reasons provided in the response to the previous Office Action and which are incorporated herein. Nonetheless, Applicants have amended their

claims in an effort to expedite prosecution of the application. The amendments are intended to merely add consistency to certain portions of the claims, and they are not related to patentability of the claims. The amended claims continue to satisfy the written requirements of 35 U.S.C. § 112, first paragraph.

In the Office Action, the Examiner asserts that “the rejected claims comprise a set of promoters that can be derived from any source to drive expression of any gene in any organism (e.g., humans, archaebacteria, etc.) or any combination of organisms (e.g., meeting the claim’s functional limitations in both humans and fish, or humans and *S. aureus*).” See Office Action, page 3. However, as the Examiner concedes in the Office Action, “[t]he instant specification describes consensus promoter sequences observed in a few different prokaryotic or eukaryotic microorganisms (e.g., *L. lactis*, *E. coli*, *S. cerevisiae*) and describes experiments wherein a range of different promoter activities in different microorganisms is obtained.” Along these lines, Applicants wish to further point out the several examples showing the promoter sets for various *microorganisms*. For instance, Examples 1 and 2 on pages 17 to 27 of the specification specifically provide a set of promoter sequences for *L. lactis*, and Example 7 on pages 31-34 of the specification specifically provide a set of promoter sequences for *Saccharomyces cerevisiae*. Further examples are provided concerning other bacteria, such as *Bacillus subtilis*, *Pseudomonas* and *E. coli*, and various exemplary methodologies for constructing the promoter sequences in accordance with the claimed invention, as well.

The claims, as herein amended, now specifically recite organisms that the Examiner has indicated are supported by the examples of the specification. For example, claim 1 recites “a microorganism selected from the group consisting of lactic acid bacteria, *Bacillus*, *E. coli*, *Pseudomonas* and yeast.” The claims also recite specific conserved sequences for bacteria and yeast.

Thus, the claims specifically recite structural characteristics (i.e., a double stranded DNA sequence, the sense strands of which comprise at least two conserved sequences identified in the specifically recited microorganisms and the conserved

sequences are restricted to specific sequences for bacterium and yeast) and functional characteristics (i.e., a range of promoter activities in steps, each step changing the promoter activity by 50-100%) and that this is coupled with a “disclosed correlation between function and structure” (i.e, a set of sequences that optimizes expression of a gene in a selected microorganism). Therefore, there is more than adequate structural/functional basis for one of skill in the art to envision the claimed promoter sets.

For at least the foregoing reasons, a person of skill in the art would reasonably conclude Applicants were indeed in possession of the claimed invention. Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH
(LACK OF ENABLEMENT)

In the Office Action, the Examiner rejects claim 18 under 35 U.S.C. § 112, first paragraph. The Examiner alleges that “the specification, while being enabling for embodiments featuring promoter sets that regulate expression of a desired gene in an organism, does not reasonably provide enablement for any embodiment wherein the flux of a cellular metabolite is controlled.” Office Action, page 7.

Applicants submit that the claims prior to their amendment herein were enabled by the specification. Nonetheless, Applicants have amended their claims in an effort to expedite prosecution of the application. The amendments are intended to merely add consistency to certain portions of the claims, and they are not related to patentability of the claims. The amended claims continue to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

In particular, claim 18 is amended herein to recite that the method is directed to expression of at least one gene product rather than the flux of a cellular metabolite. This is consistent with the Examiner’s recognition that the specification is “enabling for

embodiments featuring promoter sets that regulate expression of a desired gene." Office Action, page 7. Accordingly, Applicants respectfully submit that the ground for rejection is moot in view of the foregoing amendments. A person of ordinary skill in the art can clearly practice the full scope of the claimed subject matter without having to conduct any undue experimentation. For at least the foregoing reasons, claim 18 is enabled by the specification. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

REQUEST FOR ALLOWANCE

For at least the reasons detailed above, Applicants respectfully submit that all of the claims in the application are patentable. Favorable consideration, entry of this amendment, and issuance of a notice of allowance are respectively requested. In the event any issues remain, the Examiner is encouraged to contact applicants' representatives to resolve such issues in an expeditious manner, and place the application in condition for allowance. In the event any fees are incurred upon the filing of these documents, please charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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